REMARKS

Initially, it is noted that the Examiner has indicated that claims 23-24 contain allowable subject matter. Applicant has incorporated the subject matter of dependent claim 23 into independent claim 26. It is now believed that independent claim 26 is in proper form for allowance and such action is earnestly solicited.

Claim 24 depends from claim 26 and further defines a microfluidic device not shown or suggested in the art. It is believed that claim 24 is allowable as depending from the allowable base claim and in view of the subject matter of the claim.

The Examiner has rejected claims 21 and 26-28 for a variety of reasons. More specifically, the Examiner has rejected claims 21 and 26 under 35 U.S.C. § 102(e) as being anticipated by Ziaie et al., U.S. Patent Application No. 2004/0248326. In addition, the Examiner has rejected claims 21 and 27-28 under 35 U.S.C. § 103(a) as being unpatentable over Kriesel et al., U. S. Patent No. 6,416,495 in view of Kriesel et al. U.S. 5,693,018. Claim 26 has also been rejected under 35 U.S.C. § 103(a) as being unpatentable over Kriesel et al. '495 patent in view of the Kriesel et al. '018 patent and the Ziaie et al. '326 application. Finally, claims 21 and 26 have been rejected under 35 U.S.C. 103(a) as being unpatentable over the Eckenhoff et al. U.S. Patent No. 4,552,561 in view of the Ziaie et al., '326 application. As hereinafter described, applicant has amended independent claims 21 and 27 to more particularly define the invention for which protection is sought. Favorable consideration of claims 21 and 27-28 is respectfully sought in view of the following comments.

Claim 21 defines a microfluidic device for delivering a drug to an individual. The device includes a body defining a chamber for receiving an aqueous solution therein and including a membrane for defining a reservoir. The membrane isolates the reservoir from the chamber. An output needle has an input in communication with the reservoir and an output receivable within the individual. An adhesive is provided for affixing the body to the

individual. A pressure source including a hydrogel member is received within the chamber. The hydrogel member is expandable in response to exposure to the aqueous solution. The hydrogel member is engageable with the reservoir and urges the drug from the reservoir through the output needle as the hydrogel member expands. A valve interconnects the reservoir and the output needle. The valve is movable between a non-actuated position wherein the valve prevents the flow of the drug from the reservoir to the output needle and an actuated position wherein the valve allows for the flow of the drug from the reservoir to the output needle.

As noted in the specification (page 8, lines 28+), the aqueous solution may be injected into the chamber either during or after fabrication. As such, applicant has amended claim 21 to incorporate the injection device. More specifically, claim 21 now requires a conduit having an input communicating with the aqueous solution and an output. The conduit has a first configuration wherein the aqueous solution is isolated from the chamber and a second configuration wherein the aqueous solution communicates with the chamber. As hereinafter described, nothing in any of the cited references shows or suggests a microfluidic device incorporating such a structure.

The '326 application discloses a plurality of hydrogel actuated devices that are used for controlled drug delivery either in response to a predetermined stimulus or for pulsating delivery. It is noted, however, that the device is implantable such that actuation of the hydrogel is accomplished by diffusion of the aqueous solution thorough a porous membrane. There is no suggestion or teaching in the '326 application to provide a microfluidic device for delivering drugs wherein a pressure source includes a hydrogel within a chamber such that:

the hydrogel expands in response to an aqueous solution provided to the chamber through a conduit; and

the conduit has a first configuration wherein the aqueous solution is isolated from the chamber and a second configuration wherein aqueous solution communicates with the chamber through the conduit, as required by independent claim 21.

The Kriesel et al. '495 patent discloses an implantable fluid delivery apparatus for infusing medical fluids into a patient. The apparatus includes a bolus delivery system including a magnetically responsive polymer gel which, upon being stimulated by an electro-magnet, delivers precise bolus doses of medicinal fluids to a patient. It is noted that the apparatus disclosed in the '495 patent is implantable. Hence, it is contemplated for the polymer gel to be responsive to a singular external stimuli, e.g., magnetic stimulus or electro-magnetic waves. This structure differs substantially from the microfluidic device defined in independent claim 21. More specifically, the hydrogel defined in claim 21 is responsive to an aqueous solution provided for in the chamber in which the hydrogel member resides through a conduit, the conduit having a first configuration wherein aqueous solution is isolated from the chamber and a second configuration wherein the aqueous solution communicates with the chamber through the conduit. Nothing in the method in the '495 patent shows or suggests a structure. Further, modifying the apparatus disclosed in the '495 patent to provide a microfluidic device incorporating such a conduit would require significant modification to the prior art device, as well as, significant experimentation. As hereinafter described, the subdermal delivery device disclosed in the '018 patent cannot cure the deficiencies of the Kriesel et al. '495 patent.

The Kriesel et al. '018 patent is directed to a subdermal delivery device that includes a needle and an adhesive for affixing the device to an individual. Nothing in the '018 patent shows or suggests a hydrogel pressure source responsive to a predetermined parametcr of an aqueous solution. Further, nothing in the '018 patent shows or suggest the hydrogel pressure source being housed in a chamber or an aqueous solution being provided in the chamber in which the hydrogel member resides through a conduit, the conduit having a first configuration wherein aqueous solution is isolated from the chamber and a second configuration wherein the aqueous solution communicates with the chamber. Hence, the combination suggested by the Examiner does not teach the microfluidic device of claim 21.

Finally, the Eckenhoff et al. '561 patent discloses a self-contained body mounted pump assembly for continuously administering a therapeutic agent. The pump has a transparent top through which the contents can be seen. The pump assembly is driven by a fluid imbibing, preferably osmotic pump, and contains its own source of actuating fluid (namely, hydrogel 18). The liquid component of hydrogel 18 diffuses through wall 16 and dissolves the osmagent 15 in pump 11. The saturated solution formed within pump 11 is emitted steadily though outlet 17 to cause displacement partition 10 to be steadily forced into chamber 25 to displace the contents thereof. Again, there is no suggestion or teaching in the '561 patent to provide a microfluidic device for delivering drugs wherein a pressure source includes a hydrogel within a chamber. The hydrogel expands in response to an aqueous solution provided to the chamber through a conduit. The conduit has a first configuration wherein the aqueous solution is isolated from the chamber and a second configuration wherein the aqueous solution communicates with the chamber through the conduit, as required by independent claim 21. Further, as noted above, the '326 application cannot cure the deficiencies of the '561 patent since there is no suggestion or teaching in the '326 application to provide such a structure.

In view of the foregoing, it is believed that independent claim 21 now defines over the cited references and is in proper form for allowance.

Claim 27 defines a microfluidic device for delivering a drug to an individual. The microfluidic device includes a body defining a chamber for receiving an aqueous solution therein and including a membrane for defining a reservoir. The membrane isolates the reservoir from the chamber. An output needle has an input in communication with the reservoir and an output receivable within the individual. An adhesive is provided for affixing the body to the individual. A pressure source including a hydrogel member is expandable in response to exposure to a predetermined physical property. The hydrogel member engages the reservoir and urges the drug from the reservoir through the output needle as the hydrogel member expands. A valve interconnects the reservoir and the output needle. The valve is

movable between a non-actuated position when the valve prevents the flow of drug from the reservoir to the output needle and an actuated position when the valve allows for the flow of the drug to the reservoir to the output needle.

Similar to claim 21, claim 27 has been amended to specify that the microfluidic device includes a conduit having an input communicating with the predetermined physical property and an output, the conduit having a first configuration wherein the predetermined physical property is isolated from the chamber and a second configuration wherein the chamber communicates with the predetermined physical property through the conduit. As heretofore described, nothing in any of the cited references shows or suggests a microfluidic device for delivering drugs wherein a pressure source includes a hydrogel within a chamber wherein the hydrogel expands in response to an aqueous solution provided to the chamber through a conduit, the conduit having a first configuration wherein the predetermined physical property is isolated from the chamber and a second configuration wherein the chamber communicates with the predetermined physical property through the conduit. Such an arrangement is entirely absent from all of the cited references. Consequently, it is believed that independent claim 27 defines over the cited references and is in proper form for allowance.

Claim 28 depends from claim 27 and further defines a microfluidic device not shown or suggested in the cited references. More specifically, claim 28 specifies that the predetermined physical property is defined by an aqueous solution. Again, such a structure is not disclosed in the cited references. As such, it is believed that claim 28 is allowable as depending from an allowable base claim and in view of the subject matter of the claim.

In view of the foregoing, applicant believes that the present application with claims 21, 24 and 26-27 is in proper form for allowance and such action is earnestly solicited. The Director is hereby authorized to charge payment of any other fees associated with this communication or credit any overpayment to Deposit Account No. 50-1170.

Respectfully submitted,

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